Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

1. (Original) A method for eliciting an immune response against Group A streptococci, comprising administering to a patient a recombinant fusion polypeptide wherein said recombinant fusion polypeptide comprises a multivalent immunogenic portion fused to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion, wherein the multivalent immunogenic portion comprises at least two immunogenic amino-terminal polypeptides of Group A streptococcal M protein from at least two different Group A streptococcal serotypes, and wherein the immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion, thereby eliciting an immune response against Group A streptococci.

2. (Original) The method according to claim 1 wherein at least one of said immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype selected from the group consisting of 1, 2, 3, 4, 5, 6, 11, 12, 13, 14, 18, 19, 22, 24, 28, 30, 48, 49, 52, and 56.

3. (Original) The method according to claim 1 wherein the multivalent immunogenic portion of the fusion polypeptide consists of six immunogenic amino-terminal polypeptides of Group A streptococcal M protein from six different Group A streptococcal serotypes.

4. (Original) The method according to claim 3 wherein the six different Group A streptococcal serotypes are 1, 3, 5, 6, 19, and 24.

5. (Original) The method according to claim 1 wherein the multivalent immunogenic portion of the fusion polypeptide consists of ten immunogenic amino-terminal polypeptides of Group A streptococcal M protein from ten different Group A streptococcal serotypes.

6. (Original) The method according to claim 5 wherein the ten different Group A streptococcal serotypes are 1, 3, 5, 6, 18, 19, 22, 24, 28, and 30.

7. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 1.

8. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 2.

9. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 11.

10. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 13.

11. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 19.

12. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 22.

13. (Original) The method according to any one of claims 1 to 3 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 28.

14. (Original) The method according to any one of claims 1 to 3 wherein the administered fusion polypeptide elicits an immune response comprising opsonic antibodies against Group A streptococcal M protein that do not cross-react with human tissue.

15. (Original) The method according to claim 1 wherein the recombinant fusion polypeptide further comprises a marker encoded by an expression vector.

16. (Original) The method according to claim 15 wherein the expression vector is a His-tag vector.

17. (Original) The method according to claim 16 wherein the marker binds to nickel resin.

18. (Original) The method according to any one of claims 1 to 3 wherein the immunogenic polypeptides of the fusion polypeptide are joined by amino acids specified by a restriction enzyme site.

19. (Original) The method according to claim 1 wherein the patient is human.

20. (Original) The method according to claim 1 or claim 19 wherein the recombinant fusion polypeptide is administered via a subcutaneous route, an intramuscular route, or a mucosal route.

21. (Original) The method according to claim 20 wherein the recombinant fusion polypeptide is administered via an intramuscular route to a human at a concentration of 50 μg to 300 μg.

22. (Original) The method according to any one of claims 1 to 3 wherein the recombinant fusion polypeptide is further formulated with an adjuvant.

23. (Original) The method according to claim 22 wherein the adjuvant is alum.

24. (Original) The method according to claim 22 wherein the recombinant fusion polypeptide is further formulated with an immunomodulatory cofactor.

25. (Currently Amended) A method for eliciting an immune response against Group A streptococci, comprising administering to a patient a pharmaceutical composition comprising a recombinant fusion polypeptide, said fusion polypeptide comprising a multivalent immunogenic portion fused to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion, wherein the multivalent immunogenic portion comprises at least two immunogenic amino-terminal polypeptides of Group A streptococcal M protein from at least two different Group A streptococcal serotypes, and wherein the immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion~~according to claim 1~~, and a pharmaceutically acceptable excipient, carrier, stabilizer or diluent, thereby eliciting an immune response against Group A streptococci.

26. (Original) The method according to claim 25 wherein the composition further comprises an adjuvant.

27. (Original) The method according to claim 26 wherein the adjuvant is alum.

28. (Original) The method according to claim 25 or claim 26 wherein the pharmaceutically acceptable excipient, carrier, stabilizer or diluent comprises at least one of a buffer, antioxidant, carbohydrate, and chelating agent.

29. (Original) The method according to claim 25 or claim 26 wherein the composition further comprises an immunomodulatory cofactor.

30. (Original) The method according to claim 29 wherein the immunomodulatory cofactor is selected from the group consisting of IL-4, IL-10, γ-IFN, IL-2, IL-12, and IL-15.

31. (Original) The method according to claim 25 wherein at least one of said immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype selected from the group consisting of 1, 2, 3, 4, 5, 6, 11, 12, 13, 14, 18, 19, 22, 24, 28, 30, 48, 49, 52, and 56.

32. (Original) The method according to claim 25 wherein the multivalent immunogenic portion of the fusion polypeptide consists of six immunogenic amino-terminal polypeptides of Group A streptococcal M protein from six different Group A streptococcal serotypes.

33. (Original) The method according to claim 32 wherein the six different Group A streptococcal serotypes are 1, 3, 5, 6, 19, and 24.

34. (Original) The method according to claim 25 wherein the multivalent immunogenic portion of the fusion polypeptide consists of ten immunogenic amino-terminal polypeptides of Group A streptococcal M protein from ten different Group A streptococcal serotypes.

35. (Original) The method according to claim 34 wherein the ten different Group A streptococcal serotypes are 1, 3, 5, 6, 18, 19, 22, 24, 28, and 30.

36. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 1.

37. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 2.

38. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 11.

39. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 13.

40. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 19.

41. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 22.

42. (Original) The method according to claim 25 or claim 26 wherein at least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from a Group A streptococcal serotype 28.

43. (Original) The method according to claim 25 or claim 26 wherein the administered composition elicits an immune response comprising opsonic antibodies against Group A streptococcal M protein that do not cross-react with human tissue.

44. (Original) The method according to claim 25 or claim 26 wherein the recombinant fusion polypeptide further comprises a marker encoded by an expression vector.

45. (Original) The method according to claim 44 wherein the expression vector is a His-tag vector.

46. (Original) The method according to claim 45 wherein the marker binds to nickel resin.

47. (Original) The method according to claim 25 or claim 26 wherein the immunogenic polypeptides of the fusion polypeptide are joined by amino acids specified by a restriction enzyme site.

48. (Original) The method according to claim 25 wherein the patient is human.

49. (Original) The method according to claim 25 or claim 48 wherein the composition is administered via a subcutaneous route, an intramuscular route, or a mucosal route.

50. (Original) The method according to claim 49 wherein the composition is administered via an intramuscular route to a human at a concentration of 50 μg to 300 μg.

51. (Original) The method according to claim 1 or claim 25 wherein the elicited immune response is a protective immune response.